INNOVATIVE CONTRACTING FOR MEDICINES

How this phenomenon is evolving globally, and how AI can help with successful deployment

An independent perspective from a collection of contracting and payer experts using primary and secondary research

Presented by Model N

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EBOOK

CONTENTS

Innovative contracting for medicines is evolving from an experimental approach into an essential, mainstream operating model used globally to manage medicines with high-budget impact and uncertainty in real-world performance. Driving growth is several health ecosystem pressures, including:

- The rapid advancement of high-cost, single-administration "curative" cell and gene therapies (C&GTs)
- The very high price tag of rare and orphan drugs
- Increased budget scrutiny by payers due to broad geopolitical and economic pressures
- Accelerated regulatory approvals (resulting in medicines with immature data sets)

Contracting models have been prompted by low-volume, high-cost treatments such as C&GTs. These innovative contracts (ICs) shift from simple discounts to increasingly complex value-based agreements (VBAs) that align pricing with patient outcomes.

Companies are using artificial intelligence (AI) at various points in the IC workflow, from design, ideation, and modeling through risk forecasting, negotiation, and deployment. Post-contract adoption of AI includes data interrogation, collection of outcomes from pseudonymized data, contract adjudication, and rebate reconciliation.

This eBook examines the features of the IC approach in different contexts and international settings, the barriers to deployment, and how new technologies can help resolve issues, leading to more targeted and enhanced value treatment. The content draws on insights from current and former payers across multiple international markets. All perspectives have been anonymized and compiled by an independent subject-matter expert.

What are VBAs for medicines?

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What are VBAs for medicines?

VBAs, also known as value-based contracts (VBCs) and other forms of ICs for medicines, have evolved alongside the development of high-cost, low-volume treatments, such as gene therapies that are administered only once in a patient's lifetime.

Volume-based pricing simply does not work for these treatments. Maintaining the old pricing method could disincentivize marketing novel treatments for rare conditions due to the lack of feasible reimbursement models.

VBA refers to a range of agreements that may include capped spending but most often focus on clinical outcomes based on surrogate markers or other indicators of patient improvement or prespecified performance guarantees. VBAs align reimbursement and price with the value of a medicine as measured by agreed-upon parameters that reflect the therapy's clinical or economic benefits. Often, larger pharmaceutical producers have the expertise and financial muscle to develop VBAs.

Situations that may benefit from VBAs include cases where:[1]

- A product adds significant value compared to the standard of care but is more expensive.
- Substantial market competition exists among innovative therapies.
- There's uncertainty about the product's value.
- Budget impact is high; the list price is very high.

[1] Daniel Huang, PharmD, and Rasheed Mohammed, PharmD, MPh. "Exploring the Trend of Value-based Contracts in the United States." ForHealth Consulting at UMass Chan Medical School. February 27, 2023.

Table 1

Types of VBAs[2]

Type	Examples	Description	Strengths	Weaknesses
Finance-based agreements link payments to utilization or clinical data to reflect a therapy's value	Discount and rebates	List prices are reduced to an acceptable value; details are often confidential	Simple and fastest route to market	Blunt and relatively inflexible instrument
	Installment or annuity payments	Costs are spread over time or multiple financial years	Reduced risk through upfront payment	Legislative barriers can prevent staggered payments due to reporting and accounting rules
	Subscription model	Lump-sum payment to manufacturers grants unlimited access to a therapy for determined period	Predictable manufacturer revenues and payer budget impacts	The payer may be required to accept more risk upfront, should demand be lower than expected
Outcomes-based agreements link payments to real-world outcomes of the therapy	Population-level coverage with evidence	Addresses clinical and financial uncertainty through real-world evidence	Manages uncertainty via real-world evidence	Payers risk upfront overpayments should value be worse than expected Healthcare technical assessment (HTA) workload increases
	Outcomes-based rebate agreement	Upfront payment followed by manufacturer giving discounts (or rebates) if product does not meet expectations	Shares risk of treatment failure with manufacturer	High administrative burden is placed on healthcare professionals and patients to report and track outcomes Advanced data infrastructure is required

[2] E. Cooke, D. Alderson, and J. Morris. "The evolution of value-based agreements in US healthcare: barriers, opportunities, and future prospects." Cogentia, 2025.

Figure 1

Number of contracts held by U.S. pharmaceutical manufacturers with three or more VBCs since 2009[3]

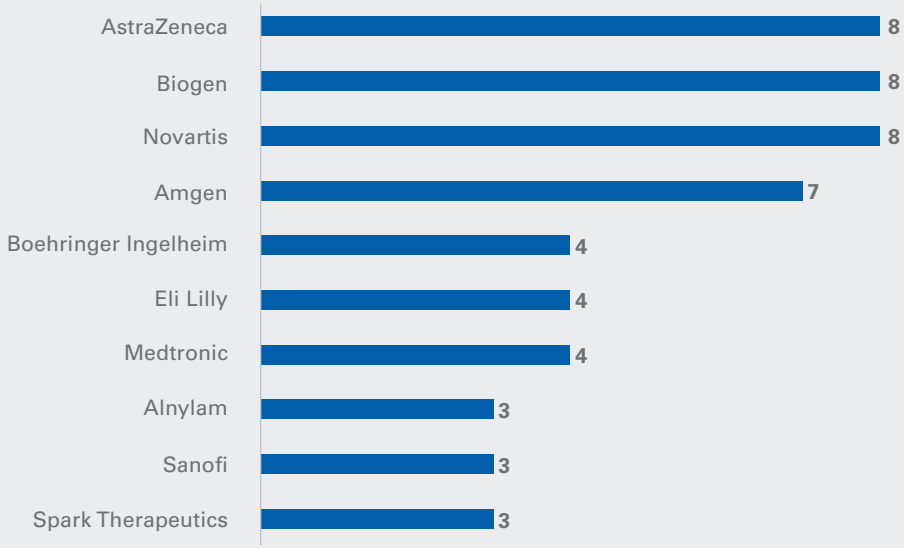
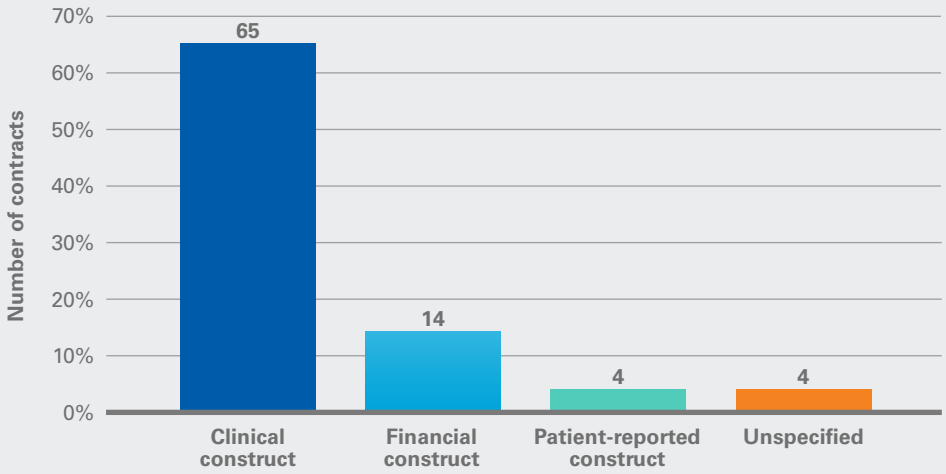


Figure 2

Construction of VBCs in the U.S. from 2009 to 2022 [4]



As seen in Figure 2, a review of VBCs in the U.S. from 2009 to 2022 revealed that 65 of 87 lacked a clinical construct with outcomes measured against clinical criteria.[4]

Of the publicly disclosed VBCs analyzed, roughly 20% were for drugs that treated neurologic (primarily multiple sclerosis) and cardiovascular (primarily hyperlipidemia) conditions, and another 25% were for endocrinologic conditions and rare diseases. This distribution is mainly driven by the chronic nature of these conditions and the lack of affordable treatment alternatives. As more manufacturers and payers collaborate in these areas, manufacturers that only offer traditional arrangements may struggle to remain competitive.

[3] Daniel Huang, PharmD, and Rasheed Mohammed, PharmD, MPh. "Exploring the Trend of Value-based Contracts in the United States." ForHealth Consulting at UMass Chan Medical School. February 27, 2023.

[4] Ibid.

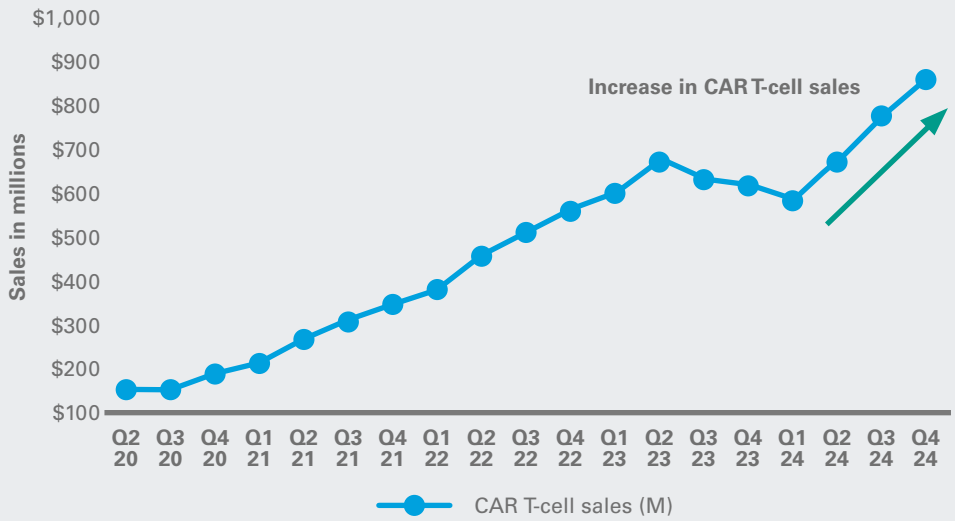
Where are VBAs used?

Early examples included a 2007 "money back" deal for Johnson & Johnson's Velcade® in the UK if the treatment for myeloma failed. In the U.S., a 2009 deal for type 2 diabetes medicines was based on blood glucose control.

Medicines, such as chimeric antigen receptor (CAR) T-cell therapy drugs (Figure 3), have also been targeted for VBAs or other ICs due to their single-dose, high-cost nature.[5]

Figure 3

CAR-T-cell U.S. sales in millions



Reports on the use of ICs across Europe, the Middle East and North Africa, and Asia-Pacific show heterogeneous growth trends, with variations in financial- versus outcomes-based contracts. Often, in nations of the Organization for Economic Co-operation and Development (OECD), service-based contracts are integrated with the aforementioned subtypes of VBAs. This represents the value these nations place on supporting healthcare infrastructure.

However, commercial interests are preventing complete transparency into the details of the contracts' agreements and operationalization. Indeed, the level of "discount" is obfuscated by the unknown performance-related reimbursement commercial terms.

[5] Dan Winkelman. "Growth of Value-Based Purchasing and Contracting for Cell and Gene Therapies (C&GTs)." IQVIA. May 2025.

Evolving trends in VBAs

With healthcare costs being squeezed worldwide, innovation is critical for the future. Attractive VBA and IC measures are those that yield tangible benefits, such as reducing patient hospitalizations. Also attractive are once-only treatments, such as gene therapy for Hunter's syndrome, which have the potential to reduce healthcare costs for decades.

These developments will go hand in hand with advances in gene testing and the identification of disease-causing gene defects. One such example is LUXTURNA®, a gene therapy for treating vision loss from Leber congenital amaurosis or retinitis pigmentosa caused by specific mutations in the RPE65 gene.

Data is limited on how these contracts are developing, but 2025 saw a shift from pilot schemes to payers wanting to implement more ICs. The five trends of the shift are:

1. Multi-assessment and longitudinal outcome contracts
2. Installment and performance-linked payments for gene therapies
3. Hybrid models with budget caps and outcome tiers
4. Portfolio-level agreements
5. Expansion to new therapy areas

Why next-gen VBAs are the future[6]

Many pharmaceutical companies are now viewing VBAs not as a new, experimental contract, but rather as a more integrated and normal strategy driven by:

- **Patient-centered access:** Payments tied to real-world benefits accelerate uptake of transformative therapies.
- **Shared risk:** Payers and manufacturers co-invest in outcomes, de-risking breakthrough treatments.
- **Data-driven agility:** Embedded real-world evidence (RWE) loops enable contract repricing and renegotiation as evidence evolves.
- **Budget predictability:** Installment and subscription models smooth fiscal spikes.
- **Differentiation:** Early adopters gain competitive and reputational advantages in today's value-driven market.

[6] Daniel Huang, PharmD, and Rasheed Mohammed, PharmD, MPh. "Exploring the Trend of Value-based Contracts in the United States." ForHealth Consulting at UMass Chan Medical School. February 27, 2023.

ICs in the U.S. versus the rest of the world

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ICs in the U.S. versus the rest of the world

United States

The U.S. was behind in developing ICs until the mid-2010s. Gene therapy and other advanced pharmaceuticals have turbocharged progress. The U.S. now leads in model innovation, driven by demand growth.

- According to data from MMIT, payers are steadily increasing their use of VBAs.[7]
- A survey presented to the Value Based Care Council reported that "nearly one-third of respondents (34% industry, 27% payers) successfully implemented a VBA" between 2020 and 2022.[8]
- VBA use varies by therapeutic area. According to a Cogentia survey, oncology products and gene therapies were viewed as having the greatest potential for VBA use in the U.S.[9]

In early 2025, the Centers for Medicare & Medicaid Services rolled out its Cell and Gene Therapy Access Model, under which state Medicaid programs reimburse one-time gene therapies like LYFGENIA® and CASGEVY® if patients meet agreed-upon outcomes. Private insurers, such as Cigna and Evernorth, are also rolling out outcome-guarantee contracts for therapies like VYVGART® and DUPIXENT®, aligning payments with real-world response rates.

Canada

Since April 2024, Canada's Temporary Access Process (pTAP) has provided conditional reimbursement tied to ongoing real-world evidence collection. As of 2025, it is now fully operational for oncology and rare diseases. Ontario and British Columbia are piloting pay-for-performance models under pTAP, with early case studies showing time-to-patient reductions of over 10 months for therapies such as epcoritamab.

United Kingdom and Europe

Managed entry agreements and HTAs are commonplace across Europe. Additionally, many European countries are exploring value-based pricing (VBP), often through risk-sharing agreements or performance-based rebates, especially for innovative or high-cost treatments where efficacy may require real-world proof.

Italy, Spain, and the UK are more experienced with outcomes-based agreements, whereas Germany and France generally price based on additional medical benefits. Germany has tentatively piloted VBAs for gene therapies, and France has adopted dynamic pricing based on RWE. However, regulatory and legislative changes may increase the adoption of more innovative contracting methodologies.

The UK's Cancer Drugs Fund, later mirrored by the Innovative Medicines Fund, facilitated dynamic pricing models in which a conditional reimbursed price would be revised downstream based on a drug's real-world performance.

[7] Heather Roulston. "Key Trends in Medical Benefit Contracting and Value-Based Agreements." Drug Channels. April 7, 2023.

[8] Jane F. Barlow, MD, MPH, MBA; Michael A. Ford, R.Ph.; and Ellen F. Licking, M.Phil. "Major Trends in Innovative Contracting: A Survey of Payers and Industry." Journal of Managed Care Medicine. January 2023.

[9] E. Cooke, D. Alderson, and J. Morris. "The evolution of value-based agreements in US healthcare: barriers, opportunities, and future prospects." Cogentia, 2025.

The rest of the world

The Gulf Cooperation Council (GCC) is leading the way with pilot projects and strategic shifts across Saudi Arabia, the United Arab Emirates, Qatar, and other member countries. However, the use of ICs is less developed than in the U.S. and some European countries. Discussions on standards and approaches are still occurring. One good example, published in 2024, is a value-based paper on biosimilars in the GCC countries.[10]

Japan and South Korea both engage in HTA and cost-effectiveness analysis (CEA), but examples of more innovative contracting are scarce. High-priced drugs for conditions with unmet needs are sometimes introduced through a CEA waiver policy, in which the initial price is set, and ongoing data collection ensures the price eventually reflects the drug's proven value and cost-effectiveness.

In Australia, some success has been seen. ZOLGENSMA®, a gene therapy for spinal muscular atrophy, was commissioned under an outcome-based risk-sharing agreement that involved a substantial confidential discount and an arrangement for an unspecified rebate if the treatment failed to meet specific developmental milestones over at least five years.

A 2023 study noted that Israel applied special pricing and reimbursement agreements for multiple specific advanced therapy medicinal products (ATMPs), generally for rare or severe diseases. These drugs, often used for conditions like B-cell acute lymphoblastic leukemia, utilize these flexible agreements to manage the high upfront costs and uncertainties surrounding long-term efficacy.[11]

Summary

- While the U.S. was a slow starter, it now leads in the number and range of value-based ICs across medicine types.
- The global focus remains on HTAs and CEA rather than on true value-based contracting.
- ATMPs,[12] rare and orphan drugs, and a range of high-cost cancer medicines are the primary focus of innovative contracting due to high up-front purchase costs.

[10] Khalid A. Alnaqbi, Ahmed Al-Jedai, Mohamed Farghaly, Mohammed A.Omair, Anas Hamad, Fatemah M. A. Abutiban, Ali Al Shirawi, Hanan Al Rayes, Sarah Aldallal, Sahar Fahmy, and Steven Simoens. "Expert Consensus Recommendations on a Biosimilars Value Framework for the Gulf Cooperation Council Countries." Therapeutic Innovation & Regulatory Science. October 30, 2024.

[11] Juan-Carolos Rejon-Parrilla, Jaime Espin, Sarah Garner, Stanislav Kniazkov, and David Epstein. "Pricing and reimbursement mechanisms for advanced therapy medicinal products in 20 countries." Frontiers in Pharmacology. November 28, 2023.

[12] ATMPs are innovative medicines that use genes, cells, or tissues to treat diseases. They fall into three categories: gene therapies (using genes to fix disorders), somatic cell therapies (modifying cells to treat the individual), and tissue engineered products (using engineered cells/tissues to repair/replace). For additional reading, reference the UK Human Tissue Authority Advance Therapy Medicinal Products definitions.

IC drug archetypes

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IC drug archetypes

Cancer

In a 2023 review,[13] most publicly available VBCs in oncology were from the EU, with significant variability across countries and financial arrangements. Finance-based agreements were more common than performance-based agreements. The U.S. had limited publicly available VBCs in oncology; however, the total is likely underestimated, as most VBCs are not publicly disclosed.

PSK9 inhibitors and cholesterol

Outcome-based contracts have been well documented for PSK9 inhibitors. The UK has implemented population health-based contracting for inclisiran and alirocumab. In the U.S., similar deals were made with healthcare insurers.

Gene therapy

The UK's National Health Service (NHS) has agreed to a deal for the use of gene-editing therapy exagamglogene autotemcel under the trade name CASGEVY. This innovative, one-time therapy offers hope of a cure for people facing a severe form of sickle-cell anemia.

The treatment's list price is £1.65 million, but the NHS struck a deal to access it at a reduced price for taxpayers, enabling it to be offered through the Innovative Medicines Fund.

ICs have been deployed for gene therapies targeting hemophilia A and B across several European markets. These broadly follow a model of a calibrated rebate dependent upon the durability of the "curative effect" defined by cessation of the requirement for replacement blood factors.

[13] Sharma Manvi, Agrawal Neha, Khurana Vivek, and Bharmal Murtuza. "Landscape of Value-based Contracting in Oncology." Presented to ISPOR, May 7-10, 2023.

Barriers to IC adoption

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Barriers to IC adoption

Several issues have prevented ICs from being more widely introduced since the first examples were used nearly 20 years ago.

Expertise

This complex issue requires expertise from the provider and purchaser. Inevitably, skills and expertise are thinly spread. Healthcare purchasers are even less likely to have a full grasp of the health economic angles and the impacts on providers. Discussions have thus been handled by governmental organizations, which have their own limitations in relation to frontline providers.

Financial and commercial terms

Trying to strike the appropriate balance between benefits and risks for both sides is difficult and may require expertise that is not always available. Organizations do not always trust drug manufacturers, and similarly, government payers are often seen as squeezing the industry. These areas of trust and belief must be overcome if ICs are to be successful.

Resistance to risk-taking

Often, payers and manufacturers claim the other party is risk averse, unwilling to meet them halfway in the risk-sharing scenario. Payers frequently view new, innovative drug launches as price gouging with eye-watering list prices. Conversely, manufacturers counter with the cost of R&D, the investment into science, and patients' unmet needs. Opposing views lead to tough negotiations, resulting in hesitancy and the failure of these contracts to materialize. Payers suggest pharmaceutical manufacturers are unwilling to take on financial risk, leaving a gap between aspirational marketing messages and evidence.

Agreeing and measuring outcomes

Agreeing on outcomes can be difficult, and measuring multiple outcomes can be time-consuming and frustrating. Frequently, payers and manufacturers may be keen to embark on an IC, only to find that progress is thwarted by their inability to align on endpoints for contracting terms.

Patient confidentiality

Increased data collection about a patient and their health to ensure treatment outcomes under a VBA can lead to concerns about loss of confidentiality. This aspect must be explained in detail to the patient. There is, however, extensive worldwide experience with pseudonymization to protect identity.

Rebates

When the agreement is that treatment will be provided at a reduced cost, the issue of rebates could be divisive and complicate pricing strategies.

If IT systems track treatment costs at the individual patient level, then initial treatment may be "charged" at the normal rate. Systems may not be sophisticated enough to support retroactive reimbursement, especially if achieved through free supplies for a future patient.

Mechanisms for reimbursement or cost reduction must be transparent, easily understood from the outset, and achievable from both sides of the agreement.

A concern for many markets is that rebates may be agreed to nationally, but not always received locally at the provider level. This can diminish trust in the rebate process, leaving providers feeling penalized and unwilling to participate in such agreements.

Summary

- Internationally, expertise in ICs is in short supply.
- Financial and commercial agreements must recognize risk and outcome measures that are core to the contract, including the ability to obtain refunds.
- Information governance will be critical to ensure patient, clinician, and financial information remains confidential.

How artificial intelligence (AI) can solve for successful ICs

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How artificial intelligence (AI) can solve for successful ICs

AI supports innovative contracting by analyzing vast patient data to predict real-world outcomes, segment patient populations, automate market access strategies, and build risk-sharing models. As a result, pricing shifts beyond traditional approaches to better reflect true clinical benefit and economic value for payers and manufacturers.

Key AI applications in ICs

- **RWE analysis:** AI sifts through electronic health records (EHRs) and clinical data to prove a drug's long-term value and effectiveness in diverse patient groups, strengthening reimbursement arguments.
- **Personalized and segmented pricing:** Machine learning identifies patient subgroups that would benefit most, enabling tailored pricing tiers, performance-based contracts, and risk-sharing agreements that align with the specific value delivered.
- **Predictive modeling:** AI forecasts optimal launch prices, cost-effectiveness across systems, and potential challenges, informing strategy before market entry.
- **Automated market access:** AI streamlines strategies by analyzing regulatory data, market dynamics, and payer behavior, accelerating negotiations.
- **Natural language processing (NLP):** NLP analyzes unstructured data in health reports and EHRs to provide insights for ICs and customized recommendations for different healthcare systems.
- **Dynamic adjustments:** AI enables real-time price adjustments based on market shifts and performance data, keeping pricing nimble and relevant.

Theoretical benefits

FOR PHARMA:
Better ROI, faster market access, and stronger negotiation with payers

FOR PAYERS AND SYSTEMS:
Evidence of value, better resource allocation, and reduced waste

FOR PATIENTS:
Access to truly effective treatments and personalized care

Practical steps for implementing ICs

1. Identify the measurable outcomes that create value for the product.
2. Recruit people with developing, presenting, and negotiating ICs, including addressing data security and pricing issues.
3. Identify the key markets for the product.
4. Work out the contract details.
5. Consider piloting the IC in a small market.
6. Agree on effective anonymized or pseudonymized record-keeping to track patient outcomes and population health benefits.
7. Publish results.

Let Model N help you develop your IC strategy and capabilities.

About this eBook

This eBook presents an independent perspective developed by an experienced consultant with deep expertise supporting leading life sciences organizations. The author collaborated with current and former payers across multiple international markets to inform the content presented. All payer insights have been anonymized to respect confidentiality. The content is presented by Model N as part of our commitment to sharing expert-driven perspectives on topics impacting the life sciences industry. The views expressed are those of the contributing experts and do not necessarily reflect the views of Model N.

About Model N

For more than 25 years, Model N has been the leader in end-to-end commercialization, revenue optimization, and compliance for pharmaceutical, medtech, and high-tech innovators. With a focus on innovation and customer success, Model N helps manufacturers streamline their revenue operations and remain compliant, empowering them to deliver life-changing products to the world. Our intelligent platform, purpose-built solutions, and advanced analytics and AI automation are trusted by more than 150 of the world's leading companies across more than 120 countries.
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